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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/644,601

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Samuel Masket

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

04/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/644,601	Applicant(s) MASKET, SAMUEL	
	Examiner KATHLEEN SONNETT	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-53 is/are rejected.
- 7) ☒ Claim(s) 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/15/2008 has been entered.

Claim Objections

2. Claim 53 is objected to because of the following informalities: "a tool shaft" that appears in line 3 of the claim appears to be synonymous with the elongated shaft of claim 38 based on applicant's disclosure (and not an additional shaft of another tool) and therefore should read "said elongated shaft". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 38-48, 51, and 52** are rejected under 35 U.S.C. 102(b) as being anticipated by Lash (US 5,728,117). Lash discloses a marking tool to mark a lens capsule of an eye for a capsulotomy procedure comprising an elongated shaft having a distal end shaped and dimensioned for insertion into an anterior chamber of the eye, the shaft defining a lumen at an opening at the distal end, a marking assembly containing a resiliently flexible metallic marking

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element having a substantially ring-shaped distal portion, in a natural state, the marking assembly being slidably received in the lumen between a transport condition wherein the marking element is deformably retracted into the lumen to enable an unobstructed penetration of the shaft distal end during insertion into the eye anterior chamber and a deployed condition wherein the marking element is advanced beyond the shaft distal end enabling the marking element to expand to its natural state (figs. 3 and 4), and a transferable marking material ("35" fig. 6; col. 4 ll. 49-54). applicable to at least the substantially ring-shaped distal portion of the marking element such that the marking material is transferred to the lens capsule during non-damaging contact by the marking element therewith. Regarding the transfer of the marking material during non-damaging contact by the marking element, it is noted that the edge of the ring-shaped portion on which the marking material (35; fig. 6) is disposed is disclosed as being a sharp edge. However, it appears that any damage caused by this sharp edge is completely dependent on the pressure exerted by the user onto the ring-shaped portion. It is possible to touch the surface of the lens capsule lightly such that the capsule surface is not damaged or cut by the edge 24 of the ring-shaped portion.

5. Regarding claim 39, the ring-shaped portion has an associated size which is adjustable by the user. That is to say, when the user actuates the tool such that the ring-shaped portion is within the elongated shaft, the ring-shaped portion is one size and when it is freed from the shaft, it has another size (see figs. 2 and 3).

6. Regarding claims 40 and 41, the transferable marking material on the ring-shaped distal portion of the marking element is a dye.

7. Regarding claims 42, 43, 45, and 46, the transfer of the marking material leaves a circular ring-shaped mark on the lens formed by the marking material (see fig. 5). It is noted

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that a circle is an ellipse (with an eccentricity of 0) and therefore can be considered an elliptical shape.

8. Regarding claim 44, the ring-shaped portion is operable to be configured into a first and second shape and size (figs. 2 and 3).

9. Regarding claim 47, the ring-shaped portion is metal (col. 3 ll. 62-63) and can be considered shape-memory as it returns to an expanded shape once deployed as seen in figs. 3 and 4.

10. Regarding claim 48, the size and dimension of the elongated shaft is suitable for insertion of the delivery mechanism through a cataract incision (34) made in a cornea of the eye.

11. Regarding claim 51, the device also comprises a plunger-type marking element retraction/extension mechanism (see 14, 16, 18).

12. Regarding claim 52, the tool comprises a dye on the ring-shaped portion of the marking element.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. **Claim 49** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lash in view of Keener Jr. (US 4,732,150). Lash discloses the invention substantially as stated above including that the ring-shaped portion may be made from a metal but fails to disclose that the ring-shaped portion is made from titanium or stainless steel. However, stainless steel and titanium are well known materials in the medical arts. Furthermore, Keener Jr. teaches that stainless steel is a

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suitable material for constructing a wire looped element that is inserted into a patient's eye (col. 3 ll. 65-68). It would have been obvious to one skilled in the art to have modified Lash to construct the ring-shaped portion from stainless steel as made obvious by Keener, Jr. since stainless steel is a suitable material for resilient ring-shaped portions of ocular surgical instruments.

15. **Claim 50** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lash. Lash discloses the invention substantially as stated above but fails to disclose the retraction/extension mechanism as being screw-type. However, it is old and well known in the art to make a retraction/extension mechanism of a medical instrument a screw-type mechanism (as admitted by applicant on p. 10, ll. 8-11 of applicant's specification) in order to obtain the well known advantage of very precisely controlling the retraction or extension of the instrument. It would have been obvious to make retraction/extension mechanism of Lash a screw-type mechanism so that it too would have this advantage.

16. **Claim 53** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lash in view of Nallakrishnan (US 5,752,960). Lash discloses the invention substantially as stated above except for the marking element being contained in a plane that intersects a longitudinal axis of the elongated shaft.

17. However, Nallakrishnan teaches that it is old and well known in the art to bend the distal portion of an instrument used for ocular surgery relative to the longitudinal axis of the rest of the instrument. Such a bend is advantageous because it facilitates insertion of the distal portion of the device into a patient's eye (fig. 3; col. 5 ll. 11-17). It would have been obvious to one skilled in the art to modify the device of Lash to include that the marking element, when deployed, is at an oblique angle to the longitudinal axis of the elongated shaft as made obvious by Nallakrishnan in order to facilitate insertion of the marking element into a patient's eye.

Response to Arguments

18. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 4/1/2008

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731